Medtronic News

# Covidien's Fortrex™ PTA Balloon Receives FDA 510(k) Clearance

*Fortrex™ PTA Balloon Facilitates Arteriovenous Access in Patients Receiving Hemodialysis for Chronic Kidney Disease*

DUBLIN, Ireland--(BUSINESS WIRE)--Nov. 24, 2014-- Covidien plc (NYSE: COV) today announced U.S. Food and Drug Administration 510(k) clearance for its Fortrex™ over-the-wire (OTW) percutaneous transluminal angioplasty (PTA) balloon catheter. The Fortrex™ 0.035" OTW PTA balloon catheter —the next-generation high pressure solution to maintain arteriovenous (AV) access—is also intended for use in the peripheral vascular system. A common procedure is to maintain AV access in patients receiving hemodialysis for chronic kidney disease or end stage renal failure.

"Access to the vessel must be properly maintained to help improve long-term use of hemodialysis," said Dr Mark Turco, chief medical officer, Vascular Therapies, Covidien. "The Fortrex™ PTA balloon has been engineered to maximize the inflation of the balloon to break up the blockages and open the vessel, providing better hemodialysis access."

In 2009, more than 398,000 patients in the U.S. were treated with some form of dialysis for end-stage renal failure.1 Hemodialysis, the most common type of dialysis, is a procedure that filters waste and removes extra fluid from the blood when the kidneys are no longer healthy. AV access sites are used to provide hemodialysis to patients. However, plaque blockages at the dialysis site can limit access.

The Fortrex™ PTA balloon provides physicians with a high pressure solution to crack the short, fibrous lesions that can block AV access. Furthermore, its unique engineering provides clinicians with:

- Optimized balloon delivery: Fortrex™ PTA balloon's low tip entry profile and robust, flexible shaft design combine to enable tight tracking to the wire and successful navigation in tortuous vessels.
- Predictable and targeted treatment: The balloon material and design permit shape retention at rated burst pressure, ensuring focused pressure on the lesion for controlled, targeted and predictable treatment.
- Procedural efficiency: The combination of balloon material and wall thickness enables reliable balloon rewrap and reinsertion along with a top tier deflation time, all of which contribute to the efficiency of the procedure.

"Covidien is committed to being the clear first choice for physicians by delivering new, innovative technologies that help improve patient lives," said Brian Verrier, president, Vascular Therapies, Covidien. "The FDA clearance of the Fortrex™ PTA balloon builds on our existing PTA portfolio, providing clinicians with access to an advanced solution to improve AV access in patients being treated with hemodialysis."

About Covidien

Covidien is a global health care leader that understands the challenges faced by providers and their patients and works to address them with innovative medical technology solutions and patient care products. Inspired by patients and caregivers, Covidien's team of dedicated professionals is privileged to help save and improve lives around the world. With more than 39,000 employees, Covidien operates in 150-plus countries and had 2014 revenue of $10.7 billion. To learn more about our business visit www.covidien.com or follow us on Twitter.

1 Kidney Disease Statistics for the United States. National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC). http://kidney.niddk.nih.gov/kudiseases/pubs/kustats/

Source: Covidien plc

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